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10/722,657	11/26/2003	Mark B. Dominick	136092SV/YOD GEMS:0244	7668

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EXAMINER	
SQUIRES, ELIZA A	

ART UNIT	PAPER NUMBER
4156	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,657	DOMINICK ET AL.	
	Examiner	Art Unit	
	Eliza Squires	4156	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "50" in reference to figure 1, "64" in reference to figure 2, and "74" in reference to figure 3, see page 5, line 20, item "48" on figure 1 and page 7, line 11, and page 8, line 21. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "56", examiner interprets the item referred to as "58" in the specification to refer to item "56", it appears that this is an error propagates in the specification as "58", "60", and "62" in the drawings will appear to be referenced in the specification as "60", "62", and "64" respectively. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the

description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

1. Claim 1 is objected to because of the following informalities: line 10 recites "network, and" the comma should be amended to a semi-colon. Appropriate correction is required.

2. Claim 4 is objected to because of the following informalities: line 26 recites "for review by a service provider" the "a" should be amended to read "the" or "said". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 1-5 and 14** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the service report" in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claims 4-5 fail to rectify this defect and are therefore rejected for the same reasons.

Claim 14 recites the limitation "the network" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 15-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed towards a computer program per se, which is non-statutory. For the purposes of the examination, examiner assumes these claims to refer to a method. Also note that in order for a method to be considered a "process" under 35 U.S.C. 101, a claimed process must either: (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials). *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972). If neither of these requirements is met by the claim, the method is not a patent eligible process under 35 U.S.C. 101 and is nonstatutory subject matter.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1, 5, 6, 11, 15, and 16** are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,972,565 to *Yokoi et al.*

6. **As to claim 1,** *Yokoi* recites a method for producing a service report for a service performed on a medical device by a service provider, comprising:

operating a computer system to receive medical device data transmitted automatically to the computer system via a communications network (abstract and column 3 lines 18-27 and column 4 lines 19-47);

operating the computer system to receive service provider data transmitted automatically to the computer system via the communications network (abstract and column 3 lines 18-27, column 3 lines 45-61, and column 4 lines 19-47); and

operating the computer system to generate the service report based on the medical device data and the service provider data (abstract and column 3 lines 18-27 and column 4 lines 19-47).

7. **As to claim 5,** see the discussion of claim 1, additionally, *Yokoi* further discloses the method comprising operating the computer system to transmit the service report to a remote device for review by a service provider (column 4 lines 29-41).

8. **As to claim 6,** *Yokoi* discloses a method for facilitating the preparation of a service report for a medical device; comprising:

providing service data automatically from the medical device to a computer system via a communications network (abstract and column 3 lines 18-27 and column 4 lines 19-47);

providing service provider data automatically to the computer system via a communications network (abstract and column 3 lines 18-27, column 3 lines 45-61, and column 4 lines 19-47); and

generating a service report based on the service data and the service provider data automatically using the computer system (abstract and column 3 lines 18-27 and column 4 lines 19-47).

9. **As to claim 11,** see the discussion of claim 6, additionally, *Yokoi* discloses the method comprising transmitting the service report from the computer system to a remote device to enable a user to revise the service report (column 6, lines 6-19).

10. **As to claim 15,** examined as a method, *Yokoi* discloses a computer program, comprising:

programming instructions stored in a tangible medium, wherein the programming instructions enable a processor-based device to produce a service report for a medical device based on medical device data received automatically from the medical device and service provider data received automatically from a remote device (abstract, column 3 lines 18-27 and column 4 lines 19-47, and figure 2).

11. **As to claim 16,** examined as a method, see the discussion of claim 15, additionally, *Yokoi* discloses the program wherein the programming instructions enable the processor-based device to produce a service report containing data representative of at least one of a hardware and a software change to the medical device (column 3 lines 18-27 and column 4 lines 19-47, and figure 2).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. **Claims 2, 9, 17, and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Yokoi* in view of U.S. Patent No. 5825327 to *Krasner.*

14. **As to claim 2,** see the discussion of claim 1, however, *Yokoi* does not explicitly disclose the tracking of a service provider. *Krasner* discloses the method wherein the service provider data comprises GPS location data from a remote device transported by the service provider (column 22, lines 41-67 and column 23, lines 1-8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* with *Krasner* in order to more accurately locate and verify the location of personnel to better confirm that the service was truly rendered.

As to claim 9, see the discussion of claim 6, additionally, *Yokoi* discloses a service report (column 3, lines 14-26 and column 4 lines 42-47). However, *Yokoi* does not explicitly disclose the tracking of a service provider. *Krasner* discloses the method

wherein the service provider data comprises GPS location data for the service provider (column 22, lines 41-67 and column 23, lines 1-8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* with *Krasner* in order to more accurately locate, verify and document the location of personnel to better confirm that the service was truly rendered.

15. **As to claim 17,** examined as a method, see the discussion of claim 15 additionally, *Yokoi* discloses a service report (column 3, lines 14-26 and column 4 lines 42-47). However, the references do not explicitly disclose that GPS data is included in the service report. *Krasner* discloses the program as recited in claim 15, wherein the programming instructions enable the processor-based device to obtain GPS data for the remote device (column 22, lines 41-67 and column 23, lines 1-8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* with *Krasner* in order to more accurately locate, verify and document the location of personnel to better confirm that the service was truly rendered.

16. **As to claim 19,** see the discussion of claim 1 and 2, additionally, *Yokoi* discloses the system as recited in claim 2, wherein the system enables a user to use the remote device to revise the service report and to transmit the revised service report to the computer system via the network (column 6, lines 6-19).

17. **Claims 3, 8, 10, and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Yokoi* in view of "Reliable Design of Medical Devices" by *Richard C. Fries*.

18. **As to claim 3,** see the discussion of claim 1. However *Yokoi* does not explicitly disclose time keeping data as a service record component. *Fries* discloses the method wherein the service provider data comprises timekeeping data for the service provider (section 28.1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* with *Fries* to provide data for a meaningful analysis of product reliability as disclosed by *Fries* (section 28.1).

19. **As to claim 8,** see the discussion of claim 6, however, *Yokoi* does not explicitly disclose that a listing of parts is included in the service report. *Fries* discloses the method wherein the service report comprises a listing of parts replaced by the service provider based on the service data (section 28.1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* with *Fries* to provide data for a meaningful analysis of product reliability as disclosed by *Fries* (section 28.1).

20. **As to claim 10,** see the discussion of claim 6, however, *Yokoi* does not explicitly disclose time keeping data as a service record component. *Fries* discloses the method wherein the service report comprises service time data for the service provider (section 28.1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* with *Fries* to provide data for a meaningful analysis of product reliability as disclosed by *Fries* (section 28.1).

21. **As to claim 18,** see the discussion of claim 1. *Yokoi* discloses the program as recited in claim 1, wherein the remote device is operable to create a service report (column 3, lines 14-26 and column 4, lines 29-47)

However *Yokoi* does not disclose that time information is part of the service report. *Fries* discloses that a service report comprises tracking time used by a service provider to perform a service on the medical device and the service data comprises an indication of the time used by a service provider to perform a service on the medical device and the service data (section 28.1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* with *Fries* to provide data for a meaningful analysis of product reliability as disclosed by *Fries* (section 28.1).

22. **Claims 4, 12, 13, and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Yokoi* in view of *Kaseya* "Virtual System Administrator" website accessed for the date of 24 April 2003 via http://web.archive.org/web/20030424123138/http://www.kaseya.com/.

23. **As to claim 4,** see the discussion of claim 1, additionally, *Yokoi* discloses the method wherein the system records an alteration of at least one of medical device hardware and medical device software (abstract and column 3 lines 18-27 and column 4 lines 19-47).

However, *Yokoi* does not disclose that the device detects the alteration in the system or that the detection of the alteration is automatically transmitted. *Kaseya* discloses that the device is operable to detect an alteration of system components and

the data transmitted automatically is representative of the alteration to system components (page 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* with *Kaseya* since the knowledge of software and hardware changes may ensure required operational parameters are met (*Yokoi* column 8, lines 26-38) and that the automatic attainment of this information would reduce user error in a manual input of this information should it be forgotten or incorrectly entered.

24. **With respect to claim 12,** *Yokoi* discloses a medical information system, comprising:

a medical device comprising hardware and software, the medical device being operable to communicate with a remote computer via a communication system (column 3, lines 46-58).

However *Yokoi* does not disclose that the device is operable to detect a change in hardware and software. *Kaseya* discloses that the system is operable to detect a change in each of the hardware and the software and to automatically transmit a signal representative of the change to the remote computer (page 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* with *Kaseya* since the knowledge of software and hardware changes may ensure required operational parameters are met (*Yokoi* column 8, lines 26-38) and that the automatic attainment of this information would reduce user error in a manual input of this information should it be forgotten or incorrectly entered.

25. **With respect to claim 13,** see the discussion of claim 12, additionally, *Yokoi* discloses the medical information system wherein the medical device is a medical imaging system (column 1, lines 12-22).

26. **As to claim 14,** see the discussion of claim 12, additionally, *Yokoi* discloses the medical information system as recited in claims 12, wherein the communication system comprises the network (column 4, lines 42-47).

27. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over *Yokoi* in view of the manual published by the *FDA* last revised 1/1/97 entitled "Quality System Manual".

28. **As to claim 7,** see the discussion of claim 6, however, *Yokoi* does not disclose that the service report comprises a list of services performed. *FDA* discloses the method wherein the service report comprises a listing of services performed by the service provider based on the service provider data (service reports section, page 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* with *FDA* in order to comply with governing body regulations for contents of a service report.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliza Squires whose telephone number is (571)270-7052. The examiner can normally be reached on Monday through Friday 8 am - 4 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Kyle can be reached on 571-272-6746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eliza Squires/
Examiner, Art Unit 4156
8/8/2008

/Charles R. Kyle/
Supervisory Patent Examiner, Art Unit 4156